Mass General Brigham
Health Plan

Amyloidosis Therapies
Amvuttra (vutrisiran)
Onpattro (patisiran)
Effective 10/01/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Treatment of hereditary transthyretin mediated amyloidosis (hATTR) in adults.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Amvuttra (vutrisiran)
Polyneuropathy of hATTR amyloidosis
1. Diagnosis of polyneuropathy of hATTR amyloidosis
2. Member is ≥18 years of age
3. Documentation of baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb†
4. Appropriate dosing

Cardiomyopathy of wild-type transthyretin-mediated (ATTRwt) or hATTR amyloidosis
1. Diagnosis of cardiomyopathy of wild-type transthyretin-mediated (ATTRwt) or hATTR/ATTRv (variant transthyretin-mediated) amyloidosis
2. Member is ≥ 18 years of age
3. Prescriber is a cardiologist or consult notes from a cardiologist are provided
4. **ONE** of the following:
    a. Results from genetic testing confirming mutations in the TTR gene
    b. Presence of amyloid deposits in biopsy tissue with confirmed TTR
    c. TTR precursor protein identification by scintigraphy, immunohistochemistry, or mass spectrometry

5. **ONE** of the following:
    a. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
        i. Vyndamax/Vyndaqel (tafamidis)
        ii. Attruby (acoramidis)
    b. **ONE** of the following:
        i. NYHA Class III heart failure
        ii. Concurrent diagnosis of hATTR-PN
6. Amvuttra will NOT be used in combination with Attruby (acoramidis), Vyndamax, or Vyndaqel (tafamidis)
7. Appropriate dosing

Onpattro (patisiran)

1. Diagnosis of hATTR amyloidosis
2. Member is ≥18 years of age
3. Member's current weight (used to verify correct dosing)
4. Documentation of baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb†
5. Appropriate dosing

Continuation of Therapy

Reauthorizations will be granted with documentation of **ALL** of the following:

1. Documentation of positive response to therapy
2. For Onpattro: Updated member weight

†The polyneuropathy disability score is an additional assessment tool with ranking based on classes I-IV. Higher scores are indicative of more impaired walking ability. The classes are defined as follows:

I: preserved walking, sensory disturbances
II: impaired walking without need for a stick or crutches
IIIa: walking with one stick or crutch
IIIb: walking with two sticks or crutches
IV: confined to wheelchair or bedridden

Limitations

1. Initial and reauthorization approvals may be granted for 12 months.

References

1. Onpattro® [package insert] San Diego (CA): Alnylam Pharmaceuticals; 2021 May.
2. Hawkins PN, Ando Y, Dispenzeri A, et al. Evolving landscape in the management of transthyretin amyloidosis. Ann Med. 2015;47(8):625-38.
3. Plante-Bordeneuve V. Update in the diagnosis and management of transthyretin familial amyloid polyneuropathy. J Neurol. 2014 Jun;261(6):1227-33.
4. Benson M. Liver transplantation and transthyretin amyloidosis. Muscle Nerve. 2013. 47:157–162.
5. Adams D, Suhr OB, Hund E, et al. First European consensus for diagnosis, management, and treatment of transthyretin familial amyloid polyneuropathy. Current opinion in neurology. 2016;29 Suppl 1:S14-26.
6. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8:31.
7. Siddiqi OK, Ruberg FL. Cardiac amyloidosis: an update on pathophysiology, diagnosis, and treatment. Trends Cardiovasc Med. 2018; 28(1):10-21.

8. Gonzalez-Lopez E, Lopez-Sainz A, Garcia-Pavia P. Diagnosis and treatment of transthyretin cardiac amyloidosis. Rev Esp Cardiol. 2017; 70(11):991-1004.
9. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013; 8:31.
10. Nativi-Nicolau J, Maurer MS. Amyloidosis cardiomyopathy: update in the diagnosis and treatment of the most common types. Curr Opin Cardiol. 2018; 33(5): 571-579.
11. Brunjes DL, Castano A, Clemons A, et al. Transthyretin cardiac amyloidosis in older Americans. J Card Fail. 2016; 22(12): 996-1003.
12. Ruberg FL, Maurer MS, Judge DP, et al. Prospective evaluation of the morbidity and mortality of wilf-type and V122I mutant transthyretin amyloid cardiomyopathy: the Transthyretin Amyloidosis Cardiac Study (TRACS). Am Heart J. 2012; 164(2): 222-228.
13. Fontana M. Cardiac amyloidosis: Clinical manifestations and diagnosis. In: Basow D (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate: 2020 [cited 2021 Aug 26]. Available from: http://www.utdol.com/utd/index.do.
14. Hafeez AS, Bavry AA. Diagnosis of Transthyretin Amyloid Cardiomyopathy. Cardiol Thep. 2020 Jun;9(1):85- 85.

Review History

05/19/2021 – Created and Reviewed; separated out MH vs. Comm/Exch criteria. Effective 07/01/2021.
11/17/2021 – Reviewed and updated; added Tegsedi to policy. Matched MH UPPL effective 1/1/2022.
11/16/2022 – Reviewed and updated for Nov P&T. Matched MH UPPL. Criteria for Tegsedi updated to require a trial with either Onpattro or Amvuttra. Member stable on Tegsedi must meet initial criteria. Updated references. Effective 2/1/2023.
01/11/2023 – Reviewed and updated for Jan P&T. Admin update to Specialty limitations. No clinical changes.
03/15/23 - Review and updated for Mar P&T. Matched MH UPPL criteria. Added Amvuttra to policy. Effective 4/1/23.
06/14/23 – Reviewed and updated for P&T. Separated out based on benefit, Rx vs MB. Effective 6/30/23.
05/15/2025 – Reviewed and updated for P&T. Updated formatting and references. Effective 6/1/25.
9/10/25 – Reviewed and updated for P&T. Added ATTR-CM following an expanded indication for Amvuttra. Effective 10/1/25